

(10) **Patent No.:** US 10,612,681 B2
(45) **Date of Patent:** Apr. 7, 2020

(52) **U.S. Cl.**
CPC *F16K 27/00* (2013.01); *A23C 7/00*
(2013.01); *A61J 3/00* (2013.01); *A61M 5/1418*
(2013.01);

(58) **Field of Classification Search**
CPC Y10T 137/5283; Y10T 137/6851; F16L
3/13; F16L 3/26; A61M 5/1413; F16K
7/04; F16K 7/07

(56) **References Cited**

U.S. PATENT DOCUMENTS

2,825,524 A 3/1958 Fox
2,931,387 A 4/1960 Fleming
(Continued)

FOREIGN PATENT DOCUMENTS

DE	42 24 167	A1	1/1994
FR	2 576 386	A1	7/1986

(Continued)

(86) PCT No.: **PCT/US2016/051714**

OTHER PUBLICATIONS

BioWorks LLC Product Brochure (date: unknown), BSC: Bio Sample Cup, Safe, Sanitary Material Storage, Easton, PA 18042, www.BioWorksLLC.com (6 pages).

(Continued)

Primary Examiner — Kevin F Murphy

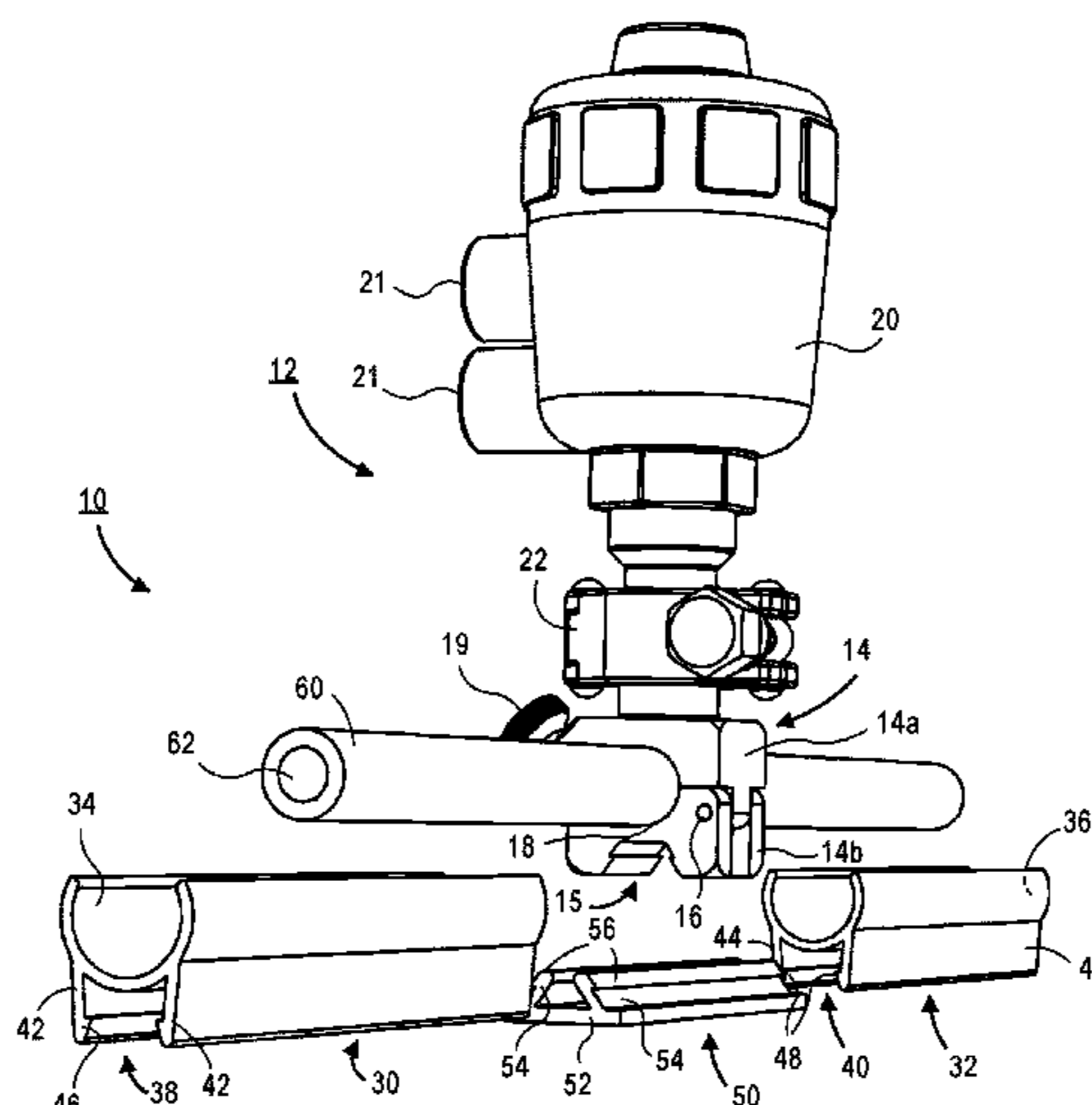
(74) *Attorney, Agent, or Firm* — Vista IP Law Group LLP

(57) **ABSTRACT**

A system for managing flexible conduit or tubing used in pharmaceutical, bioprocess, or food/dairy applications includes a segment of flexible conduit or tubing and a plurality of conduit tracks, each conduit track including a conduit channel disposed on a first side thereof and extending along the length of each respective conduit track and dimensioned to receive the segment of flexible conduit or tubing therein, each conduit track further including a con-

(Continued)

(Continued)



nector channel disposed on a second, opposing side and extending along the length of each respective conduit track and containing the one or more connectors that connect adjacent conduit tracks. The conduit tracks can be connected to each other or other process components.

17 Claims, 10 Drawing Sheets

(51) Int. Cl.

F16K 7/07 (2006.01)
A61M 5/14 (2006.01)
F16L 3/13 (2006.01)
A23C 7/00 (2006.01)
A61J 3/00 (2006.01)
A61M 39/28 (2006.01)
F16L 3/24 (2006.01)

(52) U.S. Cl.

CPC *F16K 7/07* (2013.01); *F16L 3/13* (2013.01); *A61M 5/1413* (2013.01); *A61M 39/28* (2013.01); *F16L 3/24* (2013.01); *F16L 3/26* (2013.01)

(58) Field of Classification Search

USPC 285/124.2; 248/68.1; 251/7
 See application file for complete search history.

(56) References Cited

U.S. PATENT DOCUMENTS

4,254,797 A	3/1981	Mayeaux	
4,618,114 A	10/1986	McFarland	
4,895,341 A	1/1990	Brown	
4,993,456 A	2/1991	Sule	
5,078,683 A *	1/1992	Sancoff	A61M 5/14228 604/67
5,197,708 A	3/1993	Campau	
5,350,290 A	9/1994	Honings	
5,402,823 A	4/1995	Cole	
5,549,134 A	8/1996	Browne et al.	
5,901,745 A	5/1999	Buchtel	
6,036,166 A	3/2000	Olson	
6,068,751 A	5/2000	Neukermans	
6,502,601 B2 *	1/2003	Eidsmore	F15B 13/0814 137/884
6,543,483 B2	4/2003	Johnson	
6,554,589 B2	4/2003	Grapes	
6,631,736 B2	10/2003	Seitz et al.	
6,644,353 B1	11/2003	Eidsmore	
6,976,664 B2	12/2005	Welch et al.	
7,104,275 B2	9/2006	Dille	
7,213,618 B2 *	5/2007	Milburn	F16K 27/003 137/884
7,367,363 B2	5/2008	Friedline et al.	
7,383,853 B2	6/2008	Welch et al.	
7,533,853 B2 *	5/2009	Ogawa	B60R 16/0215 248/73
8,235,067 B2	8/2012	Gagne et al.	
8,656,951 B2	2/2014	Gagne et al.	
8,979,070 B2 *	3/2015	Keizer	F16K 7/04 248/221.11

9,091,380 B2 *	7/2015	Hayashi	F16L 23/10
9,447,888 B2	9/2016	Gagne et al.	
2004/0163711 A1	8/2004	Varone	
2007/0278155 A1	12/2007	Lo et al.	
2007/0295867 A1	12/2007	Hennon	
2008/0035227 A1	2/2008	Woods et al.	
2008/0237509 A1	10/2008	Yamamoto	
2009/0120503 A1	5/2009	Donahue	
2009/0188113 A1	7/2009	McKeeth	
2012/0017733 A1	1/2012	Gay	
2012/0286110 A1 *	11/2012	Hill	F16L 3/13 248/74.2

FOREIGN PATENT DOCUMENTS

FR	2 970 315 A1	7/2012
GB	1055426	1/1967
JP	2004293769 A	10/2004
WO	97/11296 A	3/1997

OTHER PUBLICATIONS

Parker Mitos Product Brochure, Mitos Free Flow Valve, Apr. 29, 2009, <http://www.mitostech.com/freelw.html> (2 pages).

PCT International Search Report for PCT/US10/34371, Applicant: AlphaBio, Inc., Form PCT/ISA/210 and 220, dated Jul. 1, 2010 (4 pages).

PCT Written Opinion of the International Search Authority for PCT/US10/34371, Applicant: AlphaBio, Inc., Form PCT/ISA/237, dated Jul. 1, 2010 (7 pages).

PCT International Preliminary Report on Patentability (Chapter I of the Patent Cooperation Treaty) for PCT/US2010/034371, Applicant: AlphaBio, Inc., Form PCT/IB/326 and 373, dated Nov. 15, 2011 (9 pages).

BioWorks LLC Catalog, Model: BSV-H250-Bo, www.BioWorksLLC.com, cited in U.S. Appl. No. 14/165,206 dated Aug. 25, 2014 (6pages).

PCT International Preliminary Report on Patentability (Chapter I of the Patent Cooperation Treaty) for PCT/US2016/051714, Applicant: Alphinity, LLC, Form PCT/IB/326 and 373, dated Mar. 29, 2018 (11pages).

The extended European search report dated Nov. 29, 2016 in European Application No. 10775392.3-1751, Applicant: Alphinity, LLC, (10pages).

Notice of Preliminary Rejection dated Dec. 14, 2016 in Korean Patent Application No. 10-2011-7027072, (11pages).

Communication from European Patent Office dated Nov. 6, 2017 in European Patent Application No. 10775392.3-1751, (7pages).

PCT International Search Report for PCT/US2016/051714, Applicant: Alphinity, LLC, Form PCT/ISA/210 and 220, dated Dec. 7, 2016 (4pages).

PCT Written Opinion of the International Search Authority for PCT/US2016/051714, Applicant: Alphinity LLC, Form PCT/ISA/237, dated Dec. 7, 2016 (9pages).

Supplementary European Search Report dated Apr. 4, 2019 for European Patent Application No. 16847224, (8pages).

Communication pursuant to Rules 70(2) and 70a(2) EPC dated Apr. 30, 2019 for European Patent Application No. 16847224, (1page).

Invitation to Respond to Written Opinion dated May 24, 2019 for Singapore Patent Application No. 11201801785W, (7pages).

Response to Written Opinion dated Oct. 8, 2019 in Singapore Patent Application No. 11201801785W, (2pages).

Response to extended European Search Report dated Nov. 11, 2019 in European Patent Application No. 16847224.9, (36 pages).

* cited by examiner

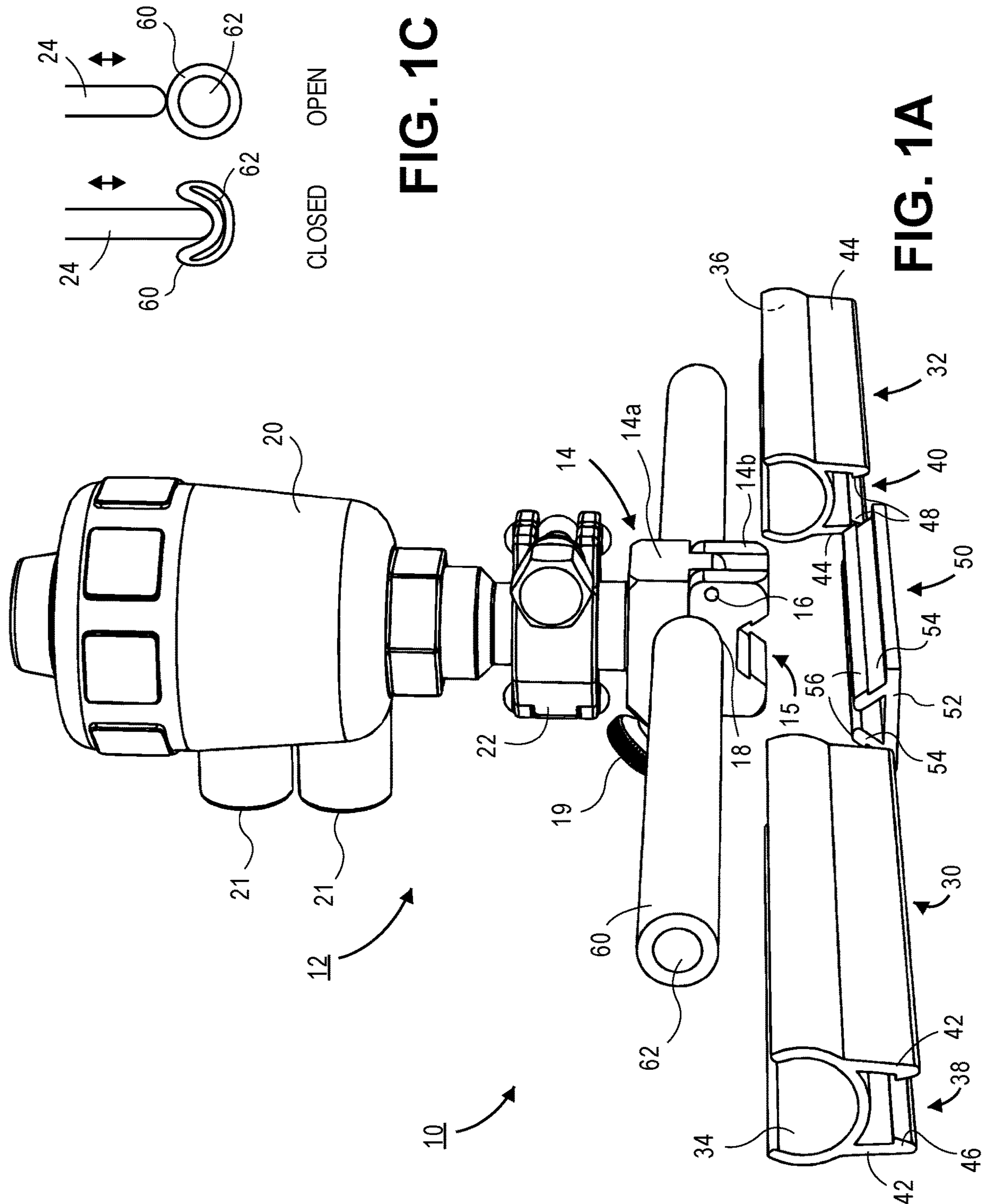


FIG. 1B

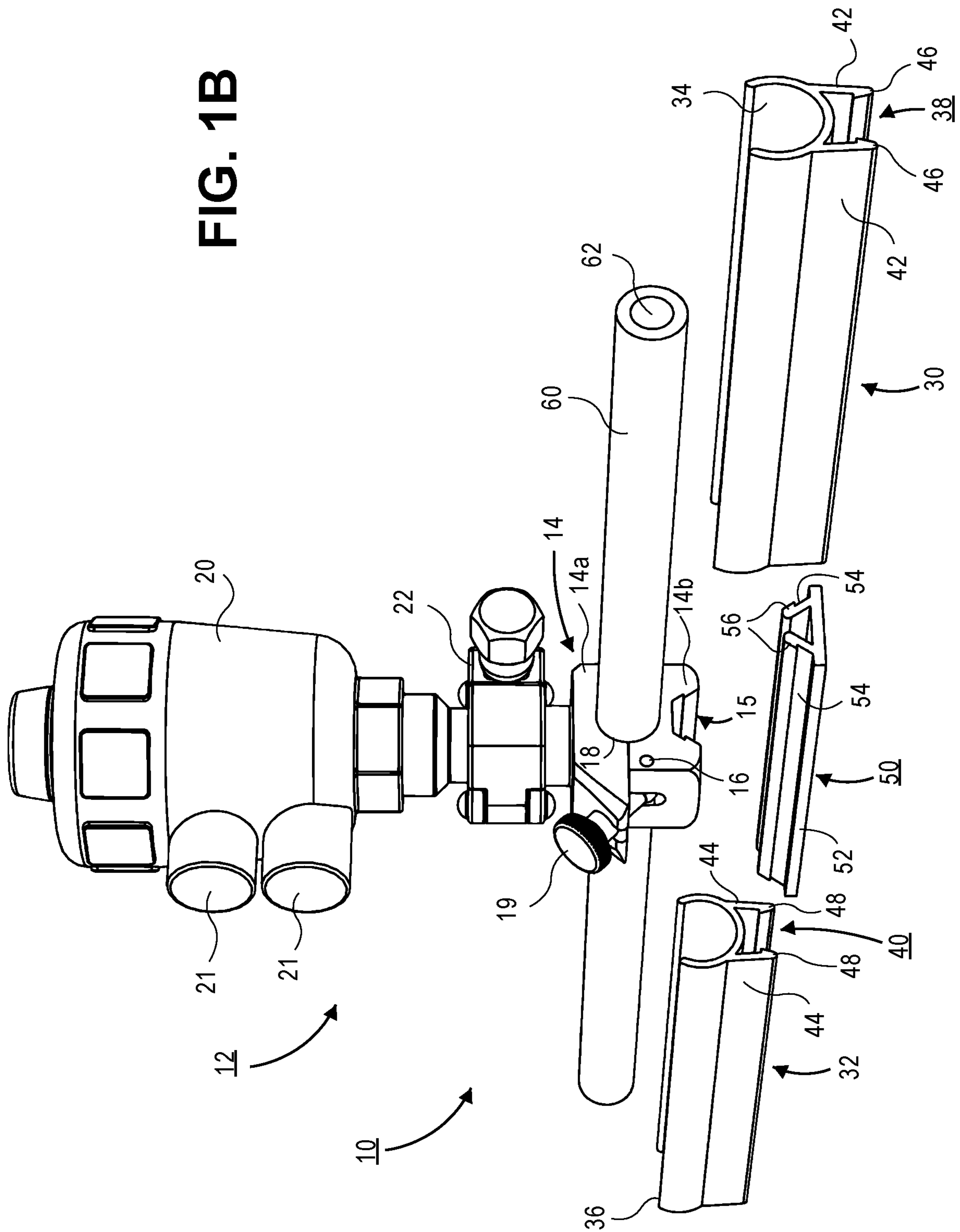
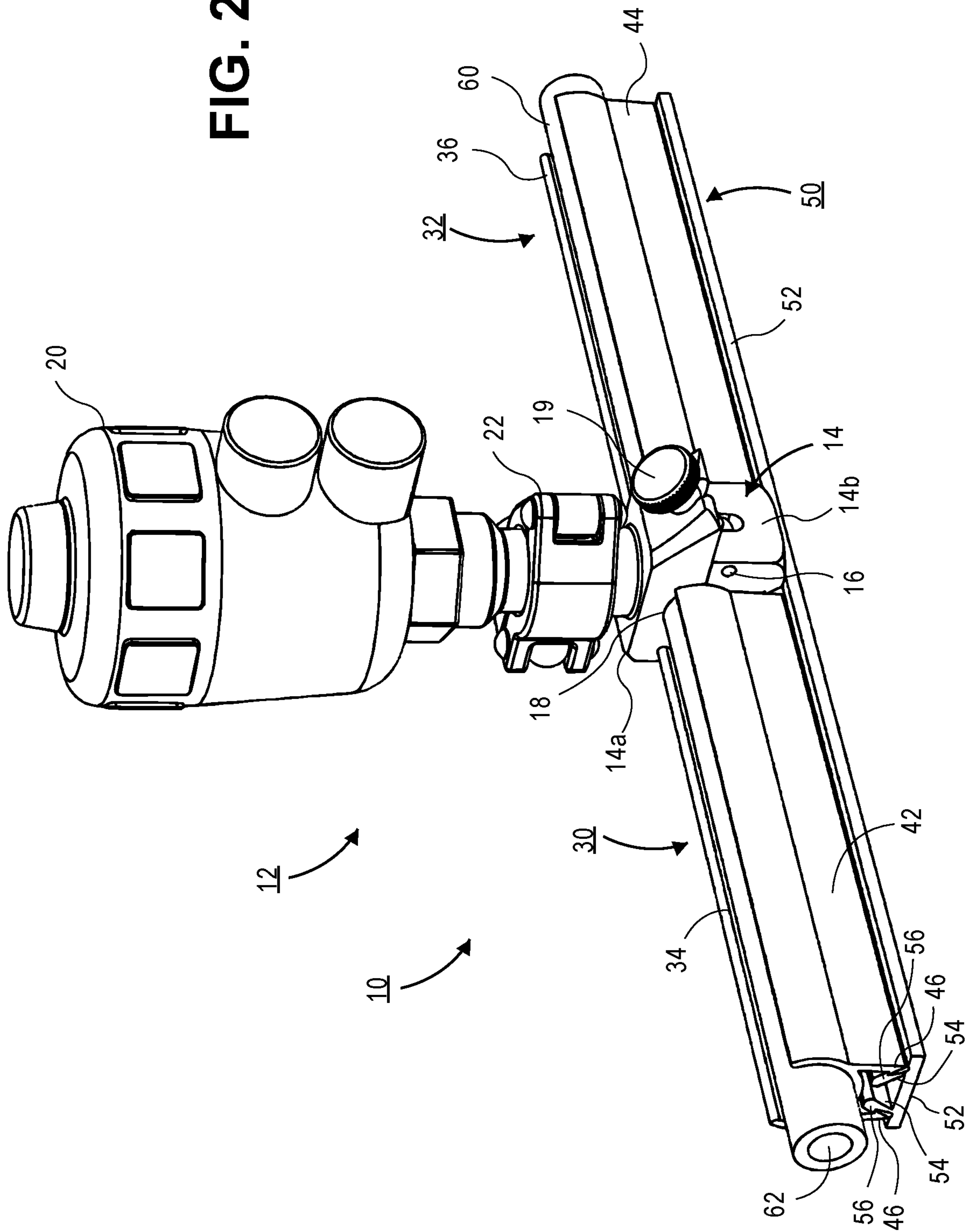


FIG. 2A



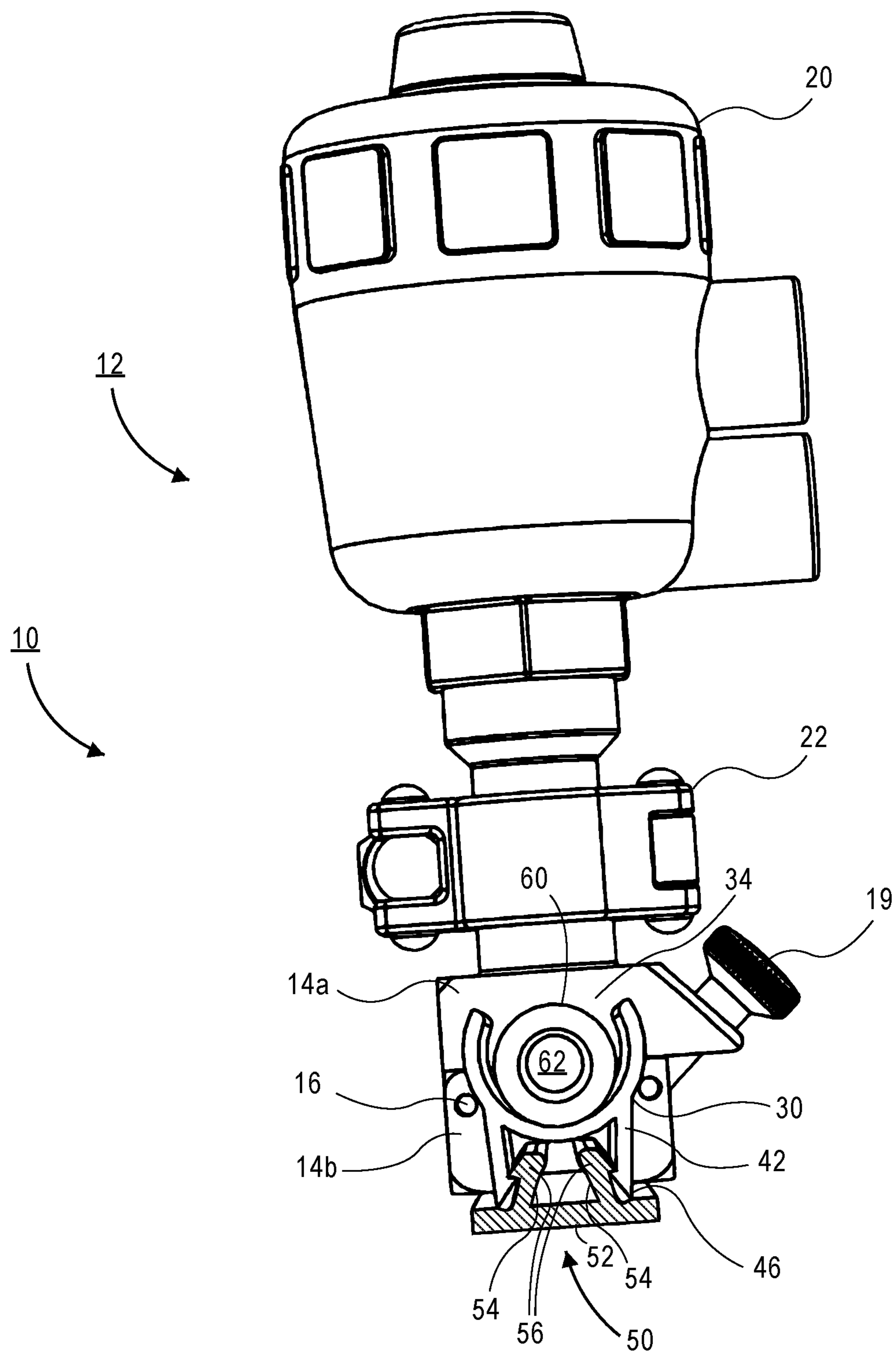


FIG. 2B

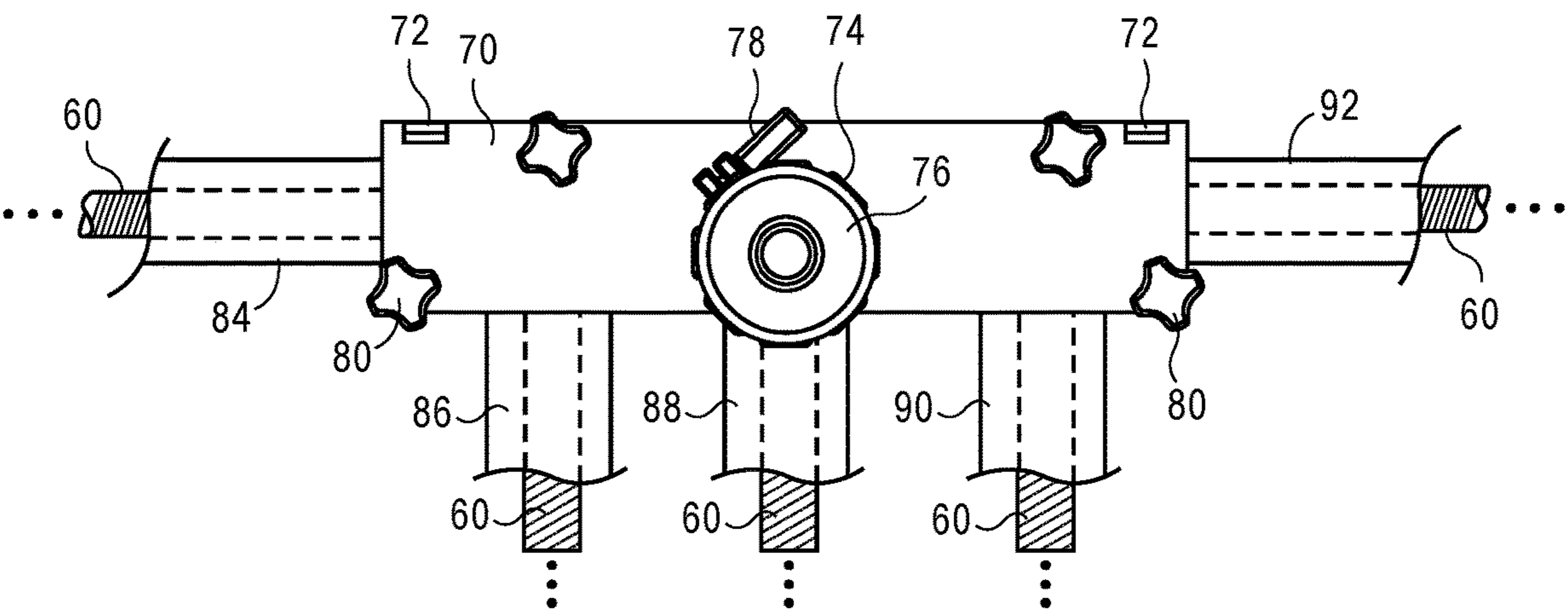


FIG. 3A

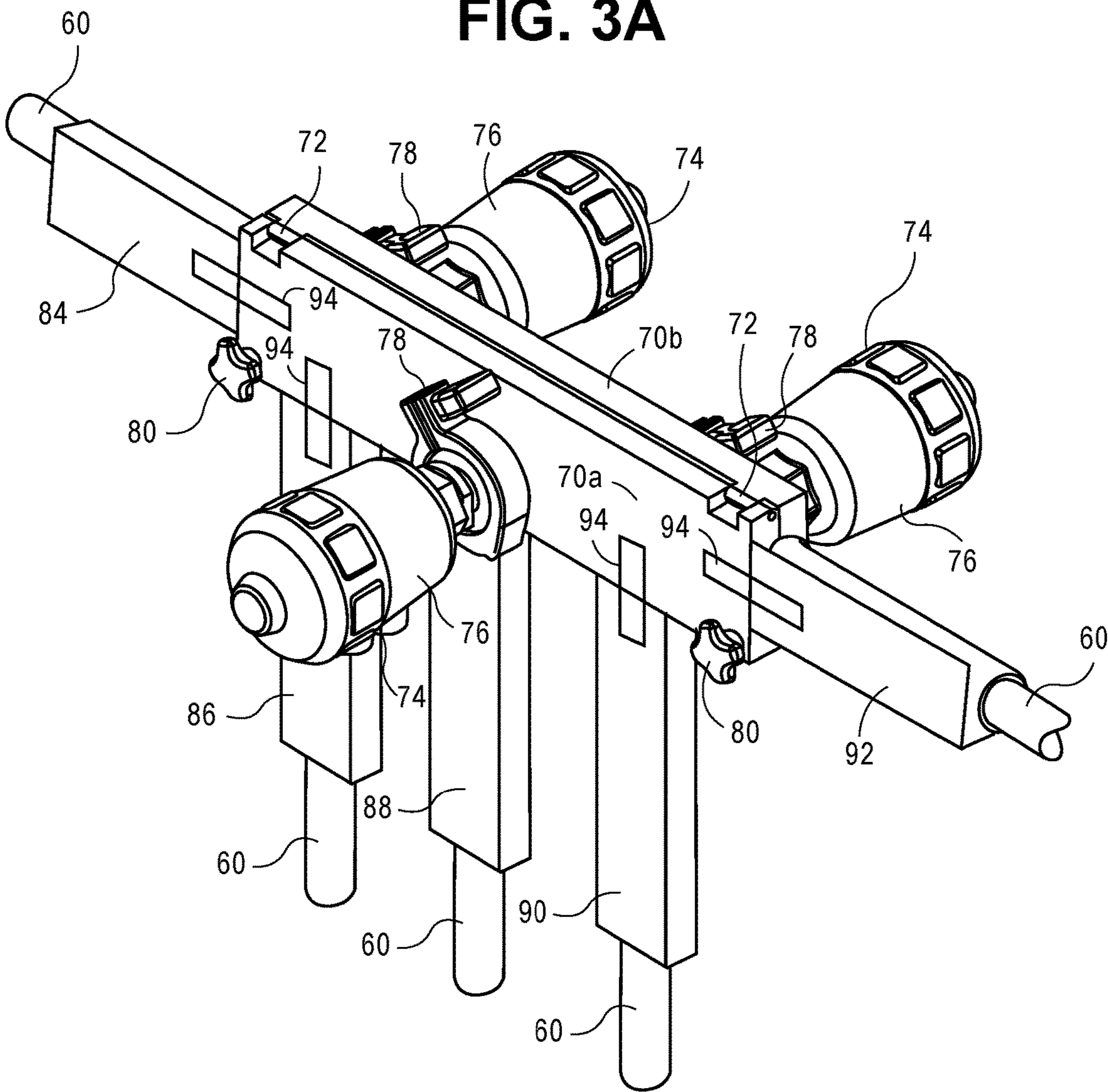


FIG. 3B

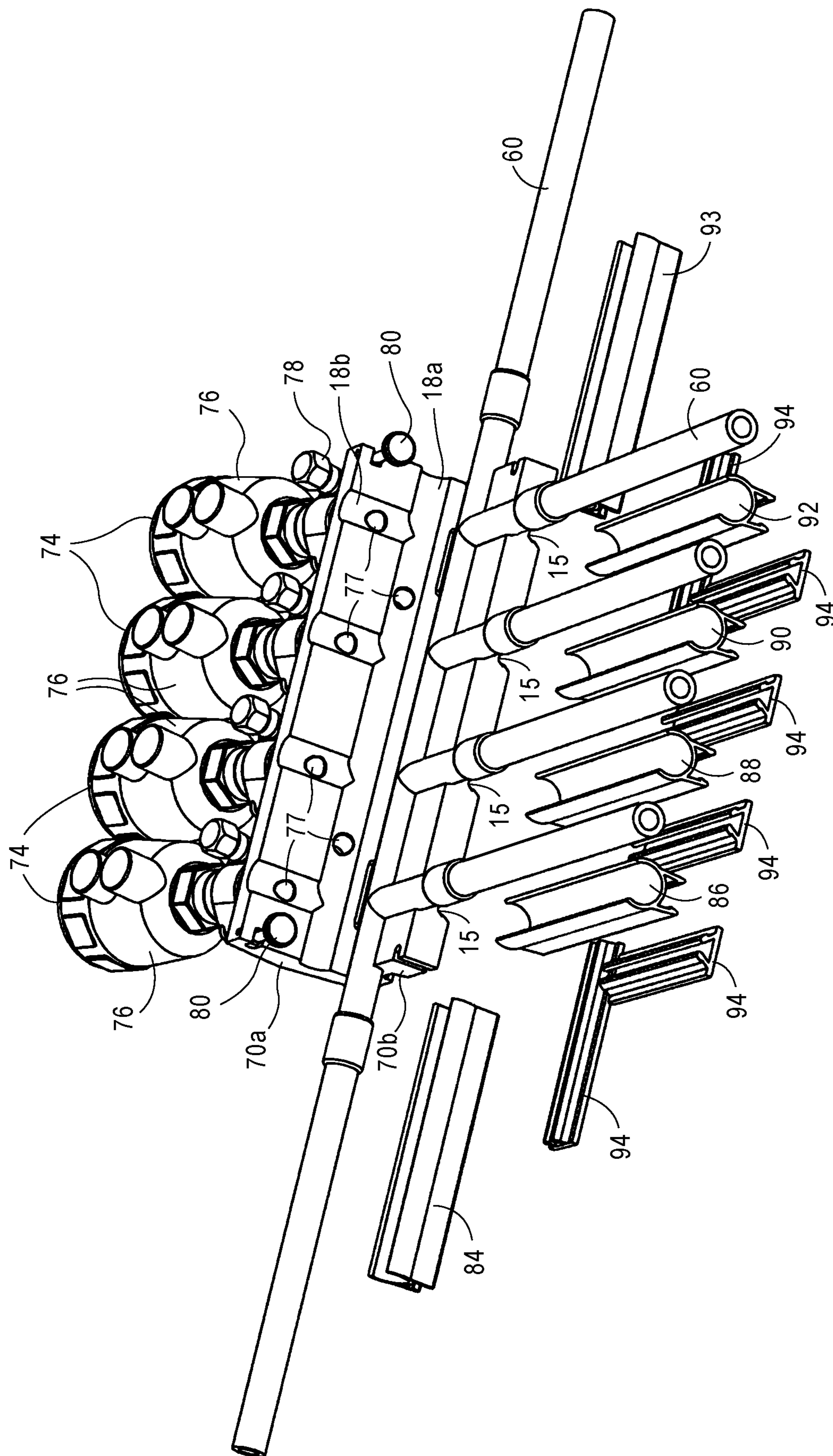


FIG. 4A

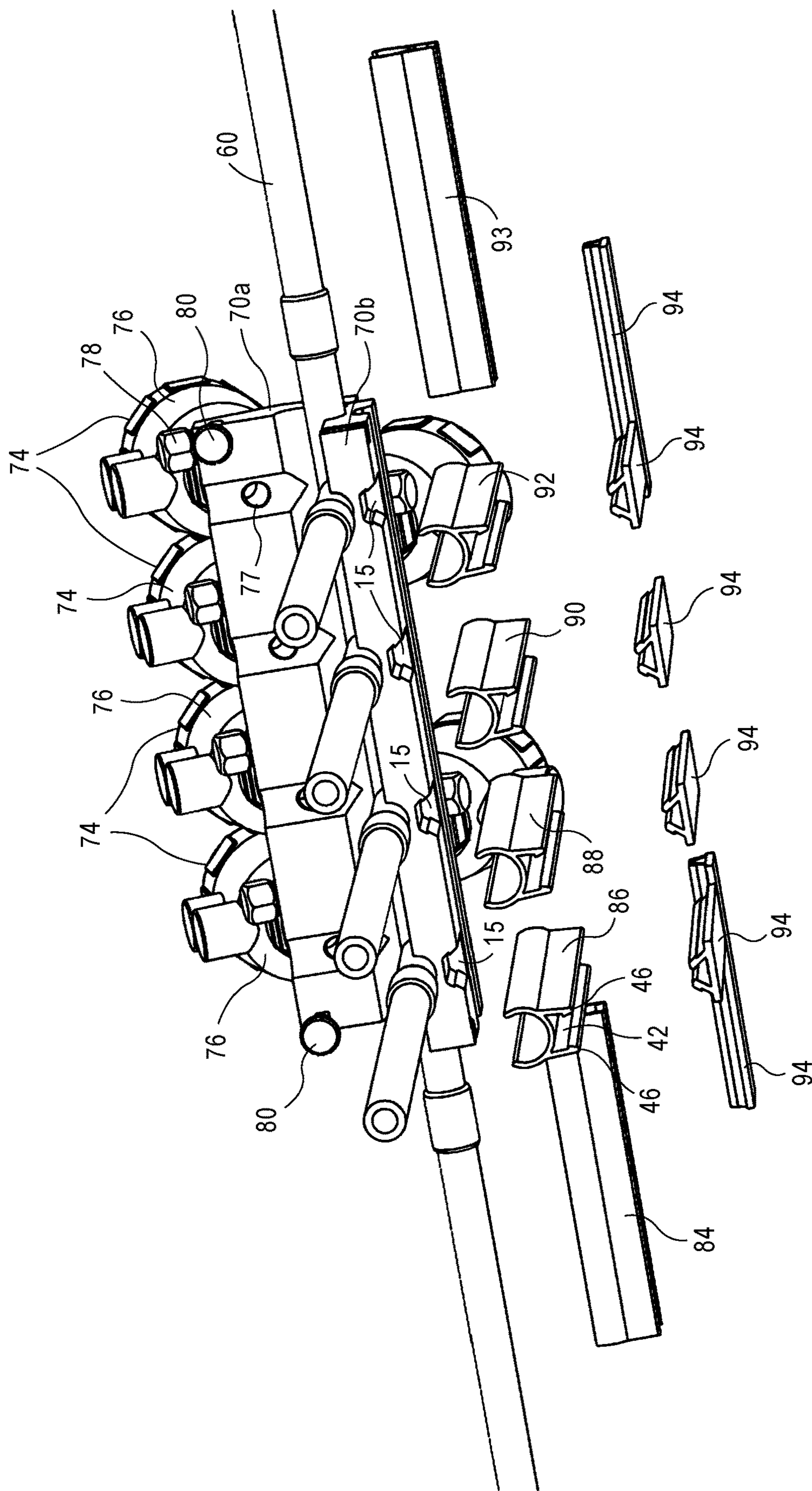


FIG. 4B

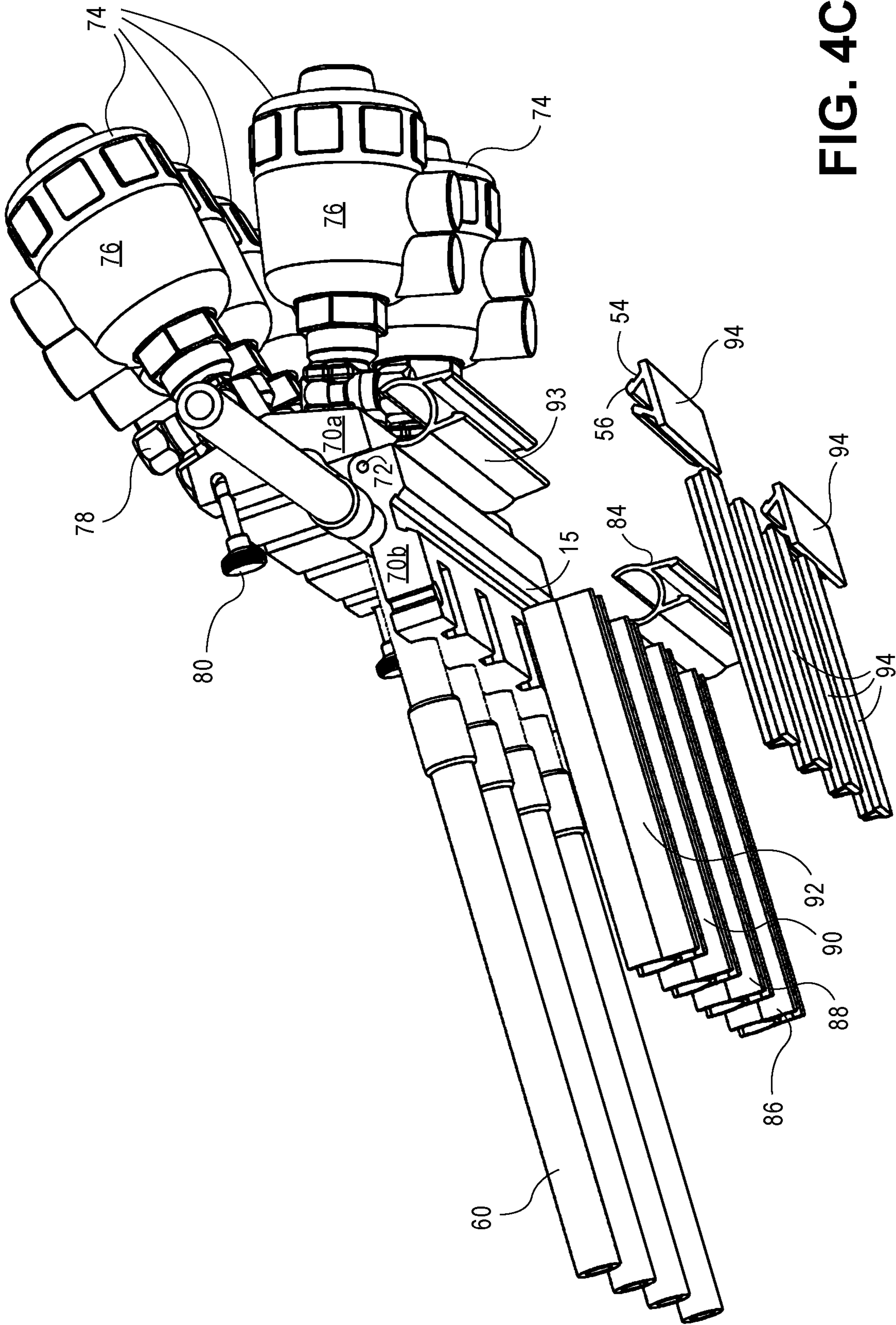


FIG. 4C

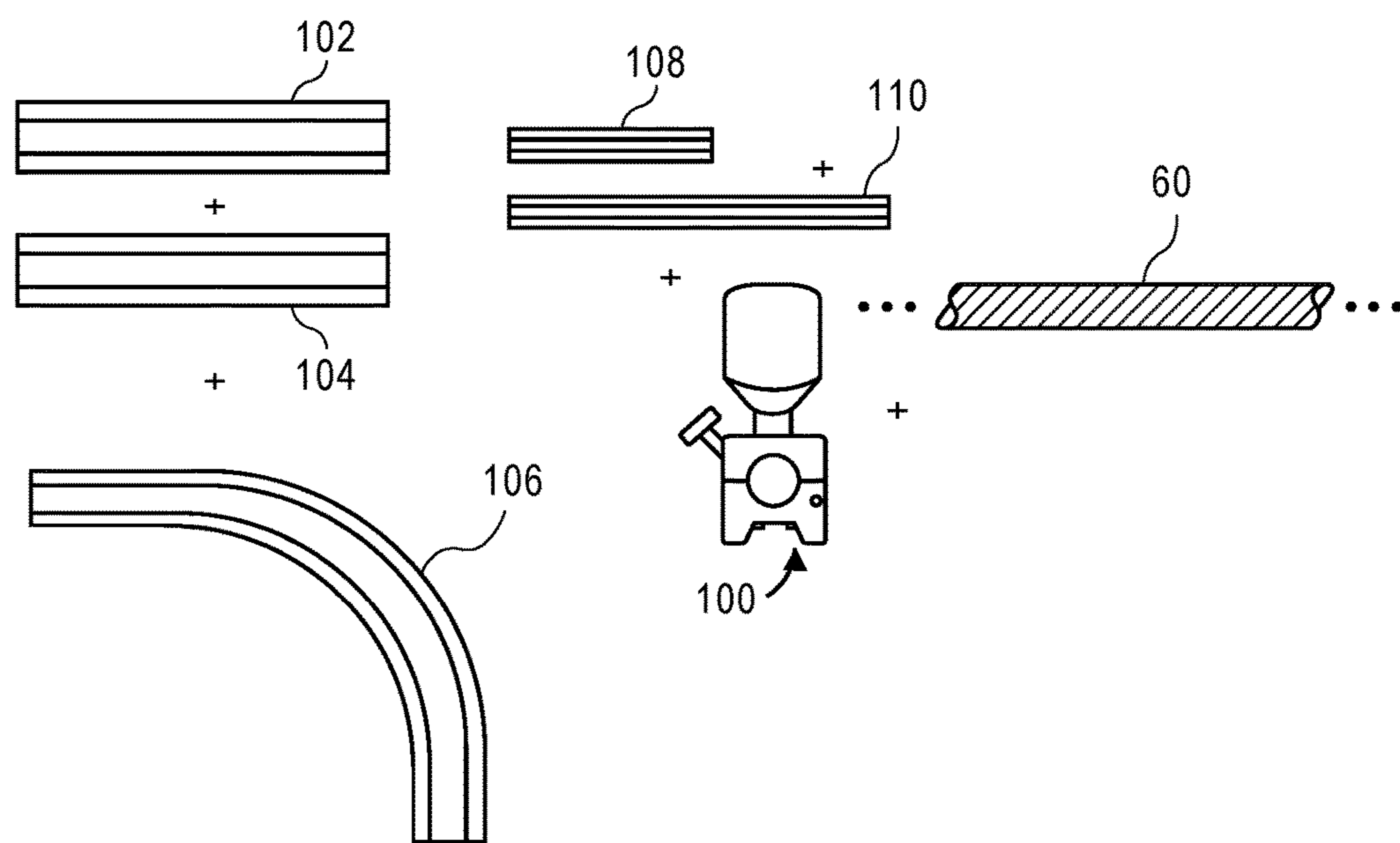


FIG. 5A

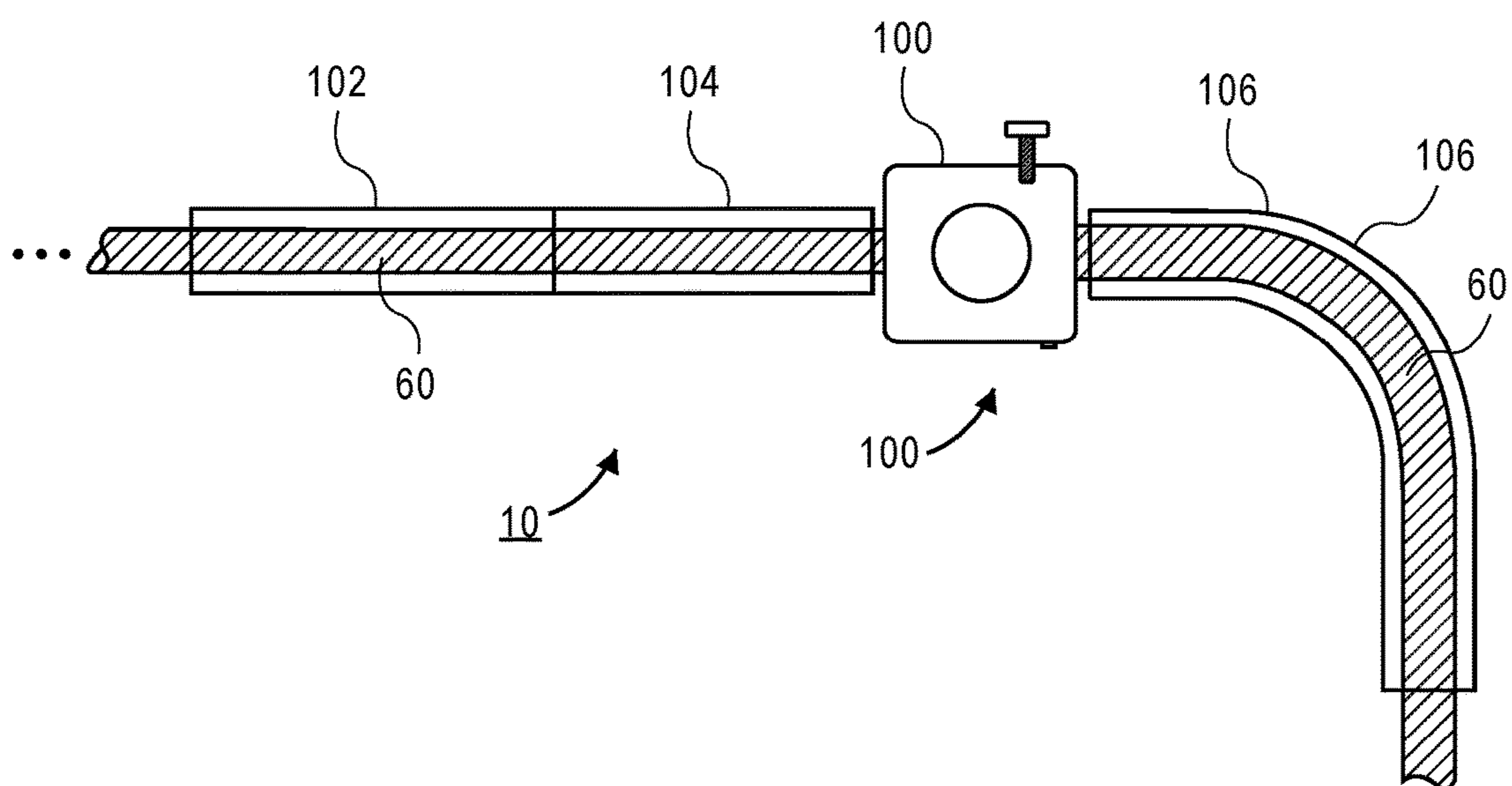


FIG. 5B

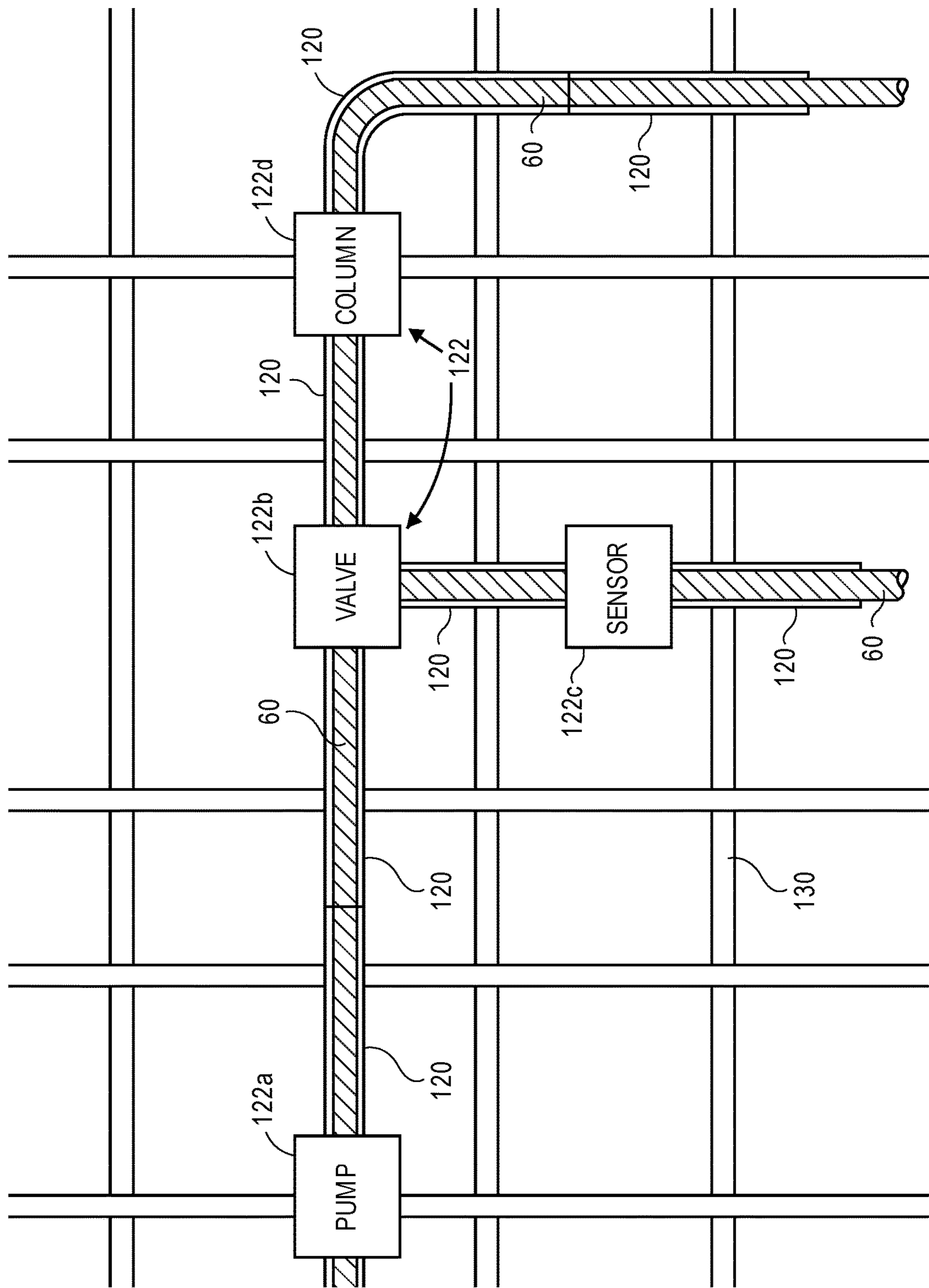


FIG. 6

1

FLEXIBLE TUBING MANAGEMENT SYSTEM FOR PHARMACEUTICAL, BIOPROCESS APPLICATIONS, AND FOOD/DAIRY APPLICATIONS

RELATED APPLICATION

This Application is a U.S. National Stage filing under 35 U.S.C. § 371 of International Application No. PCT/US2016/051714, filed Sep. 14, 2016, which claims priority to U.S. Provisional Patent Application No. 62/218,974 filed on Sep. 15, 2015, which is hereby incorporated by reference. Priority is claimed pursuant to 35 U.S.C. §§ 119, 371 and any other applicable statute.

FIELD OF THE INVENTION

The field of the invention generally relates to conduit or tubing management systems used in connection with pharmaceutical, bioprocess, or food/dairy applications.

BACKGROUND

Many commercial products are produced using chemical as well as biological processes. Pharmaceuticals, for example, are produced in commercial quantities using scaled-up reactors and other equipment. So-called biologics are drugs or other compounds that are produced or isolated from living entities such as cells or tissue. Biologics can be composed of proteins, nucleic acids, or complex combinations of these substances. They may even include living entities such as cells. In order to produce biologics on a commercial scale, sophisticated and expensive equipment is needed. In both pharmaceutical and biologics, for example, various processes need to occur before the final product is obtained. For example, in the case of biologics, cells may be grown in a growth chamber or the like and nutrients may need to be carefully modulated into the growth chamber. Waste products produced by cells may also have to be removed on a controlled basis from the fermentation chamber. As another example, biologic products produced by living cells or other organisms may need to be extracted and concentrated. This process may involve a variety of filtration and separation techniques.

Because there are a number of individual processes required to be produce the final product, various reactants, solutions, and washes are often pumped or otherwise transported to various subsystems using conduits and associated valves. This same organizational complexity may also be found in some commercial food and dairy applications. These systems may be quite cumbersome and organizationally complex due to the large numbers of conduits, valves, sensors, and the like that may be needed in such systems. Not only are these systems visually complex (e.g., resembling spaghetti) they also include many components that are required to be sterilized between uses to avoid cross-contamination issues. Indeed, the case of drug and biologic preparation, the Federal Food and Drug Administration (FDA) is becoming increasingly strict on cleaning, sterilization or bio-burden reduction procedures that are required for drug and pharmaceutical preparations. This is particularly of a concern because many of these products are often produced in batches which would require repeated cleaning, sterilization or bio-burden reduction activities on a variety of components.

More recently, disposable solutions have been proposed that utilize flexible (e.g., silicone) tubing during the manu-

2

facturing process. The flexible tubing may be discarded after use and replaced with new tubing, thereby avoiding the need to sterilize some or all of the equipment. While the use of flexible, disposable tubing provides advantages there is still the problem of managing the tubing and connected components within the overall system. As noted above, the process operations involved in pharmaceutical manufacturing and other bioprocess operations and the like are organizationally complex which require a number of different conduit segment lengths or runs that go between various components such as valves, sensors, filters, pumps, chromatography columns, elution columns, reactors, and the like. Without proper management (or even with organization) of the various tubing segments and associated process components, the system may still resemble spaghetti. Not only is this visually complex, there often are components within the system that may need to be to be adjusted, inspected, or changed-out. If there is poor organization of the system, this may interfere with the ability to properly and efficiently operate and maintain the manufacturing system. There thus is a need for a solution to better organize and manage tubing and process operations that are used in connection with pharmaceutical, bioprocess, and food/dairy manufacturing systems.

SUMMARY

In one embodiment of the invention, a system for managing flexible conduit (e.g., tubing) used in pharmaceutical, bioprocess, or food/dairy applications includes a plurality of conduit tracks which are connected either end-to-end to each other or to other process components using connectors to spatially manage and organize process components. Organizational complexity is reduced by using the conduit tracks to spatially position the flexible tubing and other components. The system is modular and can be connected in any number of desired configurations. The flexible tubing can be easily inserted into or removed from the conduit tracks which contain open channels that receive the flexible tubing. Process components such as valves, sensors, filters, elution columns, pumps, reservoirs, and the like can be integrated at appropriate points within the fluid pathway using a common mounting scheme that interfaces with the conduit tracks. The conduit tracks (and other components) can be mounted to a scaffold or support. The scaffold or support may be stationary or it may be mobile (e.g., a cart). The conduit tracks may have a number of shapes and lengths so that the fluid flow paths can be created and established in an organized and clean fashion that aids in the setup, operation, and maintenance of the system. For example, the flexible conduit or tubing that is used may be disposable and quickly swapped out and replaced with another flexible conduit or tubing. Downtime before setup and between runs is thus minimized.

In one embodiment of the invention, a system for managing flexible conduit or tubing used in pharmaceutical, bioprocess, or food/dairy applications includes a segment of flexible conduit or tubing and a plurality of conduit tracks. Each conduit track includes a conduit channel disposed on a first side thereof and extending along the length of each respective conduit track and dimensioned to receive the segment of flexible conduit or tubing therein, each conduit track further including a connector channel disposed on a second, opposing side and extending along the length of each respective conduit track and containing the one or more connectors that connect adjacent conduit tracks. The conduit tracks may also be connected to other processing components such as a pump, valve, sensor, filter, chromatography

3

column, elution column, reactor, reservoir, and manifold interposed between at least two conduit tracks.

In another embodiment, a system for managing flexible conduit or tubing used in pharmaceutical, bioprocess, or food/dairy applications includes a plurality of conduit tracks configured to connect to one another in an end-to-end fashion with one or more connectors, each conduit track including an conduit channel disposed on a first side thereof and extending along the length of each respective conduit track and dimensioned to receive a flexible conduit or tubing therein, each conduit track further including a connector channel disposed on a second, opposing side and extending along the length of each respective conduit track and containing the one or more connectors. A flexible conduit or tubing is disposed in the conduit channel.

In still another embodiment, a system for managing flexible conduit or tubing used in pharmaceutical, bioprocess, or food/dairy applications includes a valve including a hinged valve body having a first body portion and a second body portion connected to one another at a hinge, the first body portion and the second body portion defining a passageway extending through the valve body when in a closed state, the valve further including an actuator disposed on the valve body and having a pinching element configured to selectively move into and out of the passageway, wherein one of the first body portion and the second body portion includes a mounting channel disposed therein and oriented along the direction of the passageway. A flexible conduit or tubing extends through the passageway of the valve body. The system includes a first conduit track disposed on one side of the valve body, the first conduit track having a conduit channel extending along the length of the first conduit track and dimensioned to receive the flexible conduit or tubing therein, the first conduit track further including a connector channel extending along the length of the first conduit track. A second conduit track is disposed on an opposite side of the valve body, the second conduit track having a conduit channel extending along the length of the second conduit track and dimensioned to receive the flexible conduit or tubing therein, the second conduit track further having a connector channel extending along the length of the second conduit track. The system includes at least one connector disposed in the mounting channel and extends into the connector channel of the first conduit track and the connector channel of the second conduit track, wherein the valve body is secured to the connector.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1A illustrates a system for managing flexible tubing according to one embodiment. An exploded, perspective view of a single valve that is located between two segments of conduit track is illustrated. Also seen is the connector member that connects the two segments of conduit track and the valve.

FIG. 1B illustrates another exploded, perspective view of the system for managing flexible tubing illustrated in FIG. 1A.

FIG. 1C illustrates a schematic view of a valve actuator that is used to pinch flexible tubing. The pinching element extends and pinches the flexible tubing and creates a "Closed" state. When the actuator is retracted, the flexible tubing is not pinched and creates an "Open" state.

FIG. 2A illustrates a perspective view of the system for managing flexible tubing according to the embodiment of FIGS. 1A and 1B. The flexible conduit is passing through the passageway of the valve and being positioned within the

4

conduit channel of the two conduit tracks that book-end the valve. A connector extends the length of conduit tracks and valve body.

FIG. 2B illustrates an end view of the system of FIG. 2A. The flexible conduit can be seen within the conduit channel. The connector is inserted into the connector channel which is located on the opposing side of the conduit channel.

FIG. 3A illustrates another embodiment of a system for managing flexible tubing that incorporates multiple valves.

FIG. 3B is a perspective view of the system of FIG. 3A. This illustrates one valve located on one side of the valve assembly while two valves are located on an opposing side.

FIG. 4A illustrates a perspective view of another multi-valve embodiment.

FIG. 4B illustrates another perspective view of the multi-valve embodiment of FIG. 4A.

FIG. 4C illustrates yet another perspective view of the multi-valve embodiment of FIG. 4A.

FIG. 5A illustrates an embodiment in which multiple different shapes (or lengths) of conduit tracks can be combined with other process components (e.g., a valve is illustrated) to manage the location and direction of the flexible conduit. FIG. 5A illustrates the modular components prior to assembly.

FIG. 5B illustrates the assembled components of FIG. 5A.

FIG. 6 illustrates an embodiment where multiple conduit tracks are connected to one another as well as different process components and hold a flexible conduit or tubing. A scaffold or support structure is illustrated which can be used to mount the conduit tracks and/or process components.

DETAILED DESCRIPTION OF THE ILLUSTRATED EMBODIMENTS

FIGS. 1A and 1B illustrate a system **10** for managing flexible conduit (e.g., tubing) according to one embodiment. As noted herein, the system **10** has particular applicability for pharmaceutical, chemical, bioprocess, and food/dairy manufacturing operations. The system **10** is used, for example, to manage the layout and physical location of various components used in a fluid-based manufacturing process. FIGS. 1A and 1B illustrate a valve **12** being interposed between and connected to two segments of conduit track **30**, **32**. A flexible conduit **60** is illustrated and passes through the valve **12** and is secured in place to the two segments of conduit track **30**, **32** as explained below. The flexible conduit **60** is used to carry a fluid, typically although not exclusively at low pressures. The flexible conduit **60** may include silicone however other materials may be used. These include, for example, a polymer such as thermoplastic elastomers (TPE), thermoplastic rubber (TPR), or the like. The flexible conduit **60** may be unreinforced or reinforced. The flexible conduit **60** includes a central lumen through which fluid passes. The flexible conduit **60** may have a variety of sizes. For example, without limiting the invention, the flexible conduit **60** may have an internal diameter of 0.375 inches and an outer diameter of 0.625 inches. Of course, this is just illustrative and other diameters may also be used. The invention is not limited by the size of the flexible conduit **60** that is used.

Still referring to FIGS. 1A and 1B, a valve **12** is illustrated being secured around the flexible conduit **60**. The valve **12** includes a valve body **14** that is hinged via hinge **16** and forms first and second body portions **14a**, **14b**. The valve body **14** is typically made from a metallic material but it could also be formed from a suitably hard plastic or other polymer material. The first and second body portions **14a**,

5

14b, when in a closed state (as illustrated in FIGS. 1A and 1B), define a passageway 18 that extends through the valve body 14 that receives the flexible conduit 60. The first and second body portions 14a, 14b may be secured in the closed state using a fastener 19. The fastener 19 as illustrated in FIGS. 1A and 1B may include a threaded latch and knob that can be tightened or loosened on the threaded latch to selectively close/open the valve body 14. The size and shape of the passageway 18 is such that the flexible conduit 60 fits snugly therein. For example, the inner diameter of the passageway 18 may closely match the outer diameter of the flexible conduit 60. As seen in FIG. 1A, a valve actuator 20 is disposed on the valve body 14. In this embodiment, a clamp 22 is used to secure the valve actuator 20 to the valve body 14. The use of the clamp 22 is optional, however. In some embodiments, the valve actuator 20 may be directly integrated with the valve body 14. The actuator 20 includes a pinching element 24 as seen in FIG. 1C that moves in the direction of the arrow to selectively close/open the central lumen 62 of the flexible conduit 60. The actuator 20 may be moved using any number approaches. For example, the actuator 20 may be pneumatically actuated valves using air ports 21. The actuator 20 may also be manually advanced/retracted using a bonnet or the like that is manually rotated. The actuator 20 may also be actuated using a manually-activated toggle-type mechanism that does not require rotation of a bonnet or the like. This enables one to rapidly switch the valve between on/off states.

Still referring to FIGS. 1A and 1B, conduit tracks 30, 32 are illustrated adjacent to the valve 12 with each conduit track 30, 32 being located on opposing sides of the valve 12. The conduit tracks 30, 32 are used to hold the flexible conduit 60 in place in the desired spatial configuration (e.g., length, shape, and the like). The conduit tracks 30, 32 may be made of any material (e.g., polymer or plastic-based) and are typically rigid or semi-rigid. In this example, the conduit tracks 30, 32 are straight segments of track although other shapes may be used (e.g., curves, bends and the like may be integrated into the track). Each conduit track 30, 32 includes a respective conduit channel 34, 36 that extends along the length of each conduit track 30, 32 and is dimensioned to receive the flexible conduit 60. The conduit channels 34, 36 may be continuous (as illustrated) or interrupted along the length. In this embodiment, the conduit channels 34, 36 are C-shaped or semi-annular so that that flexible conduit 60 can be clipped into position. The flexible conduit 60 is pressed into the conduit channels 34, 36 and is retained by the C-shaped structure (some compression of the flexible conduit 60 during insertion and removal may occur). The opening of each conduit channel 34, 36 may be smaller than the outer diameter of the flexible conduit 60 so that the flexible conduit 60 is securely retained therein. Each conduit track 30, 32 includes a respective connector channel 38, 40 as illustrated in FIGS. 1A and 1B. The connector channel 38, 40 is located on an opposing side of the conduit channels 34, 36 in the illustrated embodiment. Each connector channel 38, 40 is formed by a pair of walls 42, 44 that extend from the conduit channels 34, 36 and terminate at respective retaining tabs 46, 48. The retaining tabs 46, 48 are used to retain a connector that is inserted into the connector channels 38, 40 as described below.

As seen in FIGS. 1A and 1B, a connector 50 is used to connect the valve body 14 to the conduit tracks 30, 32. The connector 50 may formed from a rigid piece of material (e.g., polymer, plastic-based, or even metal) that is used to connect the valve 12 to the adjacent conduit tracks 30, 32. As seen in FIGS. 1A and 1B, the connector 50 includes a

6

base 52 with a pair of retaining members 54 that extend along a length of the connector 50. The pair of retaining members 54 may include angled walls or edges as seen in FIG. 1A. The retaining members 54 may be continuous along the length of the connector 50 or they may be interrupted. The retaining members 54 in FIGS. 1A and 1B have a corresponding tab 56 along their length that engages with the corresponding tabs 46, 48 in the connector channels 38, 40. In this regard, the connector 50 is secured securely to the connector channels 38, 40 and the valve body 14. The valve body 14 includes a mounting channel 15 that is located in the valve body 14 and configured to mate with the retaining members 54 and tab 56 of the connector 50. The mounting channel 15 as illustrated in FIGS. 1A and 1B is a notched channel located in one of the two halves 14a, 14b of the valve body 14 that has notched surfaces that engage with the retaining members 54 and tab 56. The connector 50 can be inserted laterally into the connector channels 38, 40 and the mounting channel 15. Alternatively, in some embodiments, the connector 50 may be pressed directly into the connector channels 38, 40 and mounting channel 15 whereby the retaining members 54 flex and then lock into place (e.g., the connector 50 snaps into place after being pressed into the mounting channel 15 and connector channels 38, 40).

FIGS. 2A and 2B illustrate the embodiment of FIGS. 1A and 1B with the flexible conduit 60 shown inserted into the conduit channels 34, 36. The flexible conduit 60 is thus clipped or otherwise secured into place. The flexible conduit 60 may be removed from the conduit channels 34, 36 by first opening the valve body 14 using by unlocking the fastener 19. The flexible conduit 60 can then be pulled out of the conduit channels 34, 36 either laterally along the length of the channels 34, 36 or transversely by applying enough force to forcibly remove the flexible conduit 60 from the clipping structure of the conduit channels 34, 36. Also note that as best seen in FIG. 2A, in this embodiment the length of the connector 50 is such that it traverses the valve body 14 as well as the conduit tracks 30, 32. The length of the connector 50 may vary. In an alternative embodiment, multiple connectors 50 can be used to connect the conduit tracks to the valve body 14. For example, a first connector 50 that is secured to the conduit track 30 could partially extend into the mounting channel 15 while a second connector 50 that is secured to the other conduit track 32 could partially extend into the mounting channel 15.

FIGS. 3A and 3B illustrate another embodiment of a system 10 that uses a valve assembly 70 that holds multiple valves 74 secured to the valve assembly 70 using clamps 78. The valve assembly 70 is similar to the prior embodiment in that it includes a valve body having a first half 70a and a second half 70b that are connected via a hinge 72 or multiple hinges 72. The internal surfaces of the valve assembly 70 define a passageway that holds the flexible conduit 60. In this embodiment, the flexible conduit 60 includes several branches along with a main line. The passages within the first and second halves 70a, 70b thus correspond to this branched configuration and encapsulate the flexible conduit 60. The valve assembly 70 is secured in the closed state using multiple fasteners 80 like the fasteners 19 described in the prior embodiment.

In this embodiment, there are three valves 74 that are secured to the valve assembly 70. Each valve 74 has its own actuator 76 and operates a pinching element (not shown) that works as described with respect to the embodiment of FIGS. 1A, 1B to pinch the flexible conduit 60. In this embodiment, the valves 76 are located so that fluid can be selectively

switched into the various branch channels depending on which valves are opened or closed. As seen in FIGS. 3A and 3B, there are five (5) conduit tracks **84, 86, 88, 90, 92** that are connected to the valve assembly **70** and contain the flexible conduit **60** within respective conduit channels (as described previously). In this embodiment, there are separate connectors **94** that connect the various conduit tracks **84, 86, 88, 90, 92** to the valve assembly **70**. Alternatively, there could be fewer connectors if one or more connectors are lengthened and inserted into multiple conduit tracks **84, 86, 88, 90, 92**. The connectors **94** may be formed as described above in the prior embodiments and may interface with the valve assembly **70** and the conduit tracks **84, 86, 88, 90, 92** as explained previously. Alternatively, the valve assembly **70** may have connectors **94** that are permanently formed in the valve assembly **70** and interface with the conduit tracks **84, 86, 88, 90, 92**. For example, the connector **94** may include a “male” extension or connector that interfaces with corresponding “female” channels or slots formed in the conduit tracks **84, 86, 88, 90, 92** (e.g., connector channel **38, 40** of FIGS. 1A and 1B). In still another alternative construction, the conduit tracks **84, 86, 88, 90, 92** may have a male extension or connector **94** that is fixed to the respective track and interfaces with a female slot or channel (e.g., mounting channel **15** of FIGS. 1A and 1B) formed in the valve assembly **70**. These alternative designs of the connectors **94** may also be used with the embodiments described in FIGS. 1A, 1B, 2A, and 2B. While three (3) valves **76** are illustrated, there could be additional or fewer valves **76** and the invention is not limited by the number of valves **76**.

FIGS. 4A-4C illustrate another embodiment of a system **10** that has a valve assembly **70** that includes multiple valves **74** positioned thereon. In this embodiment, there are six (6) valves **74** that are disposed on or otherwise connected to the valve assembly **70**. Each valve **74** has its own actuator **76** and operates a pinching element (not shown) that works as described with respect to the embodiment of FIGS. 1A, 1B to pinch the flexible conduit **60** that is positioned between two halves **70a, 70b** of the valve assembly **70** that are connected via hinge **72**. Fasteners **80** (e.g., latches with knobs as described previously) may be used to secure the two halves **70a, 70b** of the valve assembly **70** together. In addition, optional clamps **78** may be used to secure the valves **74** to the valve assembly **70** as illustrated. Alternatively, the valves **76** may be directly incorporated into the valve assembly **70**. In this embodiment, the valves **76** are located so that fluid can be selectively switched into the various branch channels depending on which valves are opened or closed. As best seen in FIG. 4A, there are apertures **77** located in valve assembly half **70a** that allow passage of the pinching element (e.g., pinching element **24** of FIG. 1C) so that the flexible conduit **60** can be pinched (closed) or un-pinched (open). Two such apertures **77** are located in the main passageway **18a** while four apertures **77** are located in branch passageways **18b**.

As seen in FIGS. 4A-4C, there are six (6) conduit tracks **84, 86, 88, 90, 92, 93** that are connected to the valve assembly **70** and contain the flexible conduit **60** within respective conduit channels (as described previously, for example, in FIGS. 1A, 1B, 2A, 2B). In this embodiment, there are six (6) separate connectors **94** (as described previously, for example, in FIGS. 1A, 1B, 2A, 2B) that connect the various conduit tracks **84, 86, 88, 90, 92, 93** to the valve assembly **70**. As best seen in FIGS. 4B and 4C, mounting channels **15** are located in the valve assembly half **70b**. The mounting channels **15** are formed as a notched channel that has notched surfaces that engage with corresponding sur-

faces and tabs of the connectors **94** (described previously). The connectors **94** connect the respective conduit tracks **84, 86, 88, 90, 92, 93** to the valve assembly **70** via the mounting channels **15**. Note that in one alternative embodiment, a single long connector **94** could be used that connects both conduit tracks **84** and **93**.

In another alternative embodiment, the connectors **94** could be omitted from the interface between the valve assembly **70** and the conduit tracks **84, 86, 88, 90, 92, 93**. For example, the valve assembly **70** could have “connectors” integrated in the valve assembly **70**. These, for example, could include “male” extensions that are formed integrally into the valve assembly **70** and insert into the connector channels of the conduit tracks **84, 86, 88, 90, 92, 93**. In yet another alternative, the conduit tracks **84, 86, 88, 90, 92, 93** that interface with the valve assembly **70** could have “male” ends that integrate with the mounting channels **15**. These alternative embodiments would eliminate the need to have connectors **94** at the interface between the conduit tracks **84, 86, 88, 90, 92, 93** and the valve assembly **70**. Note that these alternative designs may also apply to the embodiments of FIGS. 1A, 1B, 2A, and 2B.

FIGS. 5A and 5B illustrate the modular nature of the system **10** that is described herein. Various components can be mixed and matched in various combinations and setups to achieve the desired spatial arrangement of components. In the very basic example of FIGS. 5A and 5B a single valve **100** is illustrated along with two straight conduit tracks **102, 104** and a curved segment of conduit track **106**. Two connectors **108, 110** are also illustrated. To achieve the final configuration of FIG. 5B, the two straight conduit tracks **102, 104** are connected to one another using the connector **108**. The other connector **110** connects to one end of the straight conduit track (e.g., conduit track **104**) and extends through the valve **100** (e.g. using a mount channel **15** of the type illustrated in FIG. 1A) and connects with the curved segment of conduit track **106**. Of course, this example just illustrates a very small portion of the overall hierarchy of the system. Once can imagine that a full manufacturing process will have many different components that are connected together. Thus, many conduit tracks of a variety of different sizes, shapes, and geometries can be employed. Further, while the embodiments described herein have utilized a valve or multiple valves positioned between different conduit tracks there could be other components that are connected to conduit tracks. This includes, for example, pumps, sensors, filters, chromatography columns, reaction volumes (e.g., reactor), reservoirs, manifolds, and the like.

The conduit tracks with the flexible conduit **60** contained therein may be optionally mounted on a support or scaffold to further aid in spatially arranging components. The support or scaffold may be secured to the ground, ceiling (e.g., hung), or on the walls of a manufacturing facility. The scaffolding or support could also be located on a moveable cart or the like for other applications. The conduit tracks could be mounted using a variety of different fasteners such as zip ties, clips, screws, or even adhesives. FIG. 6 illustrates an embodiment where multiple conduit tracks **120** are connected to one another as well as different process components **122**. Illustrated process components **122** include a pump **122a**, valve **122b**, sensor **122c**, and column **122d**, although other process components may be included. A flexible conduit or tubing **60** is illustrated being mounted in the conduit tracks **120** and passing through the various process components **122**. In this embodiment, a scaffold or support **130** is also illustrated that can be used to mount the conduit tracks **120** and/or the process components **122**.

As seen in the embodiments described herein, the various conduit tracks are seen as being located adjacent to the valve body or valve assembly. Note that these adjacent conduit tracks need not necessarily abut with the valve body or valve assembly. There may be a gap between an adjacent conduit track and the valve body/valve assembly. Of course, in other embodiments, the conduit tracks may physically abut with the valve body/valve assembly. Moreover, while the valve body/valve assembly has been described as interfacing with a connector, in some alternative embodiments, the valve body/valve assembly may be secured directly to the conduit track without the need for a separate connector. In addition, in the illustrated embodiments, a clamp **22, 78** is shown connecting the various valves **12, 74** and actuators **20, 76** to the valve body **14** or valve assembly **70**. In some alternative embodiments, there are not clamps and the valves **12, 74** with associated actuators **20, 76** are directly secured to the valve body **14** or valve assembly **70**.

Applicant has thus described a flexible conduit management system that can be used to organize and layout flexible conduit that is used as part of a liquid-based manufacturing process. The conduit tracks are used to secure the flexible conduit in a fixed location and desired shape. Each conduit track includes a conduit channel for holding the flexible conduit. The flexible conduit can easily be loaded into and out of the conduit channel. For example, for aseptic or sterile applications, the flexible conduit can quickly be replaced with another flexible conduit while using the same conduit tracks. The conduit tracks include on an opposing side a connector channel that has walls or the like to define a slot that receives a rigid or semi-rigid connector. The connector enables the conduit tracks to be connected to other conduit tracks or other process components such as valves, pumps, filters, columns, reservoirs, sensors, and the like. For example, the process component may have a mounting channel or other slot that receives the connector so that a conduit channel can be secured relative to the process component. The connector acts as a tongue that is inserted into a slot or channel on a conduit track or other process component. Various lengths of flexible conduits can be used. For example, multiple segments of flexible conduit may be connected to one another using standard connectors such as clamps can be used. Alternatively, a long length of flexible conduit that traverses many conduit tracks and process components can be used.

In the embodiments described herein the connectors may be separate in which case they are inserted into the various connector channels on the conduit tracks or mounting channels on process components. Alternatively, the connector may be fixed to a conduit track or process component and inserted into the connector channel or mounting channel of an adjacent component. It should be understood that while various embodiments are described herein various feature of one embodiment may be combined or used with another embodiment. That is to say, features of one embodiment may be substituted or used in another embodiment. While embodiments of the present invention have been shown and described, various modifications may be made without departing from the scope of the present invention. The invention, therefore, should not be limited, except to the following claims, and their equivalents.

What is claimed is:

1. A system for managing flexible conduit or tubing used in pharmaceutical, bioprocess, or food/dairy applications comprising:

a segment of flexible silicone or polymer conduit or tubing; and

a plurality of conduit tracks, each conduit track including an open conduit channel disposed on a first side thereof and extending along the length of each respective conduit track and dimensioned to receive the segment of flexible silicone or polymer conduit or tubing therein, each conduit track further including a connector channel disposed on a second, opposing side and extending along the length of each respective conduit track and containing one or more connectors that connect adjacent conduit tracks, each connector comprising a base having a pair of angled walls or edges that extend along a length thereof and are disposed non-orthogonal to the base and having tabs formed thereon that engage with corresponding tabs in the conduit tracks.

2. The system of claim 1, further including one or more of a pump, valve, sensor, filter, chromatography column, elution column, reactor, reservoir, and manifold interposed between at least two conduit tracks.

3. The system of claim 1, wherein the open conduit channels are C-shaped or semi-annular.

4. The system of claim 1, wherein the plurality of conduit tracks and the segment of flexible conduit or tubing are mounted on a scaffold or support structure.

5. The system of claim 1, wherein the plurality of conduit tracks comprise conduit tracks of different shapes.

6. A system for managing flexible conduit or tubing used in pharmaceutical, bioprocess, or food/dairy applications comprising:

a plurality of conduit tracks configured to connect to one another in an end-to-end fashion with one or more connectors, each conduit track including an open conduit channel disposed on a first side thereof and extending along the length of each respective conduit track and dimensioned to receive a flexible silicone or polymer conduit or tubing therein, each conduit track further including a connector channel disposed on a second, opposing side and extending along the length of each respective conduit track and containing the one or more connectors;

a flexible silicone or polymer conduit or tubing disposed in the open conduit channels of the plurality of conduit tracks; and

wherein, each connector comprising a base having a pair of angled walls or edges that extend along a length thereof and are disposed non-orthogonal to the base having tabs formed thereon that engage with corresponding tabs in the conduit tracks.

7. The system of claim 6, further comprising a valve body or valve assembly containing the flexible silicone or polymer conduit or tubing therein and interfacing with one or more of the conduit tracks.

8. The system of claim 6, wherein the open conduit channel is C-shaped or semi-annular.

9. A system for managing flexible conduit or tubing used in pharmaceutical, bioprocess, or food/dairy applications comprising:

a plurality of conduit tracks configured to connect to one another in an end-to-end fashion with one or more connectors, each conduit track including a conduit channel disposed on a first side thereof and extending along the length of each respective conduit track and dimensioned to receive a flexible conduit or tubing therein, each conduit track further including a connector channel disposed on a second, opposing side and extending along the length of each respective conduit track and containing the one or more connectors;

11

a flexible conduit or tubing disposed in the conduit channels of the plurality of conduit tracks;
 a valve body or valve assembly containing the flexible conduit or tubing therein and interfacing with one or more of the conduit tracks; and, wherein the valve body or valve assembly comprises a mounting channel and wherein the connector comprises a base having a pair of retaining members extending along a length of the connector and configured to mate with the mounting channel.

10. The system of claim **9**, wherein the mounting channel comprises a notched channel and the pair of retaining members comprise a pair of walls extending from the base, the walls of the pair each having respective retaining tabs located on an edge thereof, and wherein the walls with the respective retaining tabs engage with the notched channel to secure the valve body or valve assembly to the connector.

11. A system for managing flexible conduit or tubing used in pharmaceutical, bioprocess, or food/dairy applications comprising:

a valve comprising a hinged valve body having a first body portion and a second body portion connected to one another at a hinge, the first body portion and the second body portion defining a passageway extending through the valve body when in a closed state, the valve further comprising an actuator disposed on the valve body and having a pinching element configured to selectively move into and out of the passageway, wherein one of the first body portion and the second body portion includes a mounting channel disposed therein and oriented along the direction of the passageway;

a flexible conduit or tubing extending through the passageway of the valve body;

a first conduit track disposed on one side of the valve body, the first conduit track comprising a conduit channel extending along the length of the first conduit track and dimensioned to receive the flexible conduit or tubing therein, the first conduit track further comprising a connector channel extending along the length of the first conduit track;

12

a second conduit track disposed on an opposite side of the valve body, the second conduit track comprising a conduit channel extending along the length of the second conduit track and dimensioned to receive the flexible conduit or tubing therein, the second conduit track further comprising a connector channel extending along the length of the second conduit track; and

at least one connector disposed in the mounting channel and extending into the connector channel of the first conduit track and the connector channel of the second conduit track, wherein the valve body is secured to the connector.

12. The system of claim **11**, wherein the conduit channels of the first and second conduit tracks are C-shaped or semi-annular.

13. The system of claim **11**, wherein the connector channels of the first and second conduit tracks comprise a pair of walls forming an open channel, the pair of walls each having respective retaining tabs located on an edge thereof.

14. The system of claim **13**, wherein the at least one connector comprises a base having a pair of retaining members extending along a length thereof and configured to mate with the pair of walls and retaining tabs of the connector channels.

15. The system of claim **11**, wherein the at least one connector comprises a base having a pair of retaining members extending along a length thereof and configured to mate the mounting channel.

16. The system of claim **15**, wherein the mounting channel comprises a notched channel and the pair of retaining members comprise a pair of walls extending from the base, the pair of walls each having respective retaining tabs located on an edge thereof, and wherein the walls with the respective retaining tabs engage with the notched channel to secure the valve to the rigid connector.

17. A method of using the system of claim **9**, comprising removing the segment of flexible conduit or tubing and inserting another segment of flexible conduit or tubing into the open conduit channels of the plurality of conduit tracks.

* * * * *